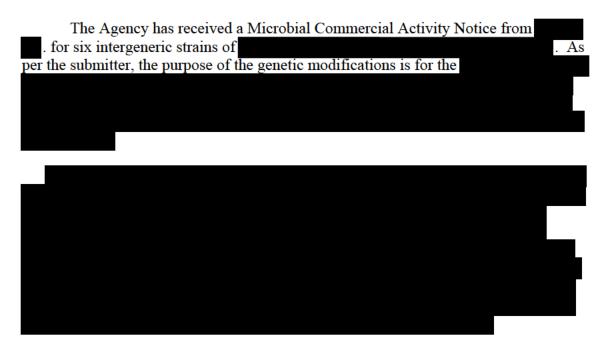
Briefing Paper Biotech MCAN J-15-0013, 0014, 0015, 0016, 0017, 0018

PART		BACKGROUND DATA Program Manager: Jesse Miller Technical Integrator: Gwen McClung Review Team: Mark Segal, Greg Macek, Alie Muneer, David Lynch, Ron Ward, Gwen McClung
		Dispo Meeting Date: June 18, 2015
A.	microon	aims: Submitter Identity, Chemical identity, Use, Recipient rganism, Donor microorganism, Genetic construct, Exposure, Production , Process information.
В.	Submit	ter:
C.	Recipie	ent Microorganism: microorganism:
D.		tion volume
	i) Max	ximum PV (Year 3):

E. Use:

PART II: Introduction



PART III: Recommendation and Rationale

Drop from further review.

There is low risk to human health and the environment associated with the production of the six intergeneric strains done to does not pose concerns.

PART IV: Risk Summary

A. Human Health Hazard

The potential health hazards of the recipient microorganism,
, have been evaluated by Ward (2015)

The recipient microorganism does not pose pathogenicity or toxicity concerns based on the 5(h)(4) risk assessment.

The submission microorganism and the introduced genetic material do not pose pathogenicity or toxicity concerns. There is a low concern for potential allergy from exposure to the submission microorganism. There is no concern for the use of antibiotic resistance genes since the used during construction of the submission microorganism were not introduced into the final submission microorganisms.

B. Ecological Hazards

There are low ecological hazard concerns for the recipient microorganism,
(Muneer, 2015). This is ubiquitous in the environment
with no known adverse effects to animals or plants or the environment. The genetic
modifications done on the recipient microorganism to arrive at the production strain do
not pose ecological concerns. Many organisms including animals, plants, and
microorganisms produce
The inserted genetic material does not pose ecological hazards. It merely
enables
The production strain may be expected to survive in the environment if inadvertently released from facilities, however, its potential survival does not pose concerns.